



MAY 24 2006

19 May 2006

Program Manager  
USDA/AMS/TMP/NOP  
1400 Independence Avenue SW  
Room 4008-So., Ag Stop 0268  
Washington, DC 20250

RECEIVED  
USDA NATIONAL  
CLEANING PROGRAM  
2006 MAY 25 PM 12:03

Dear Sir/Madam,

To assure that certain colors from natural sources remain on the NOP National List of non-organically produced ingredients we offer you the attached petitions for six different color categories.

Colors from Fruit Juices as set forth in 21 CFR 73.250  
Colors from Vegetable Juices as set forth by 21 CFR 73.260  
Beta-Carotene from natural sources as set forth by 21 CFR 73.95  
Colors from Annatto as set forth by 21 CFR 73.30  
Colors from Turmeric as set forth by 21 CFR 73.600  
Colors from Paprika as set forth by 21 CFR 73.340

We understand that these petitions for colors are now absolutely essential for the NOSB to approve them so colors remain on the National List after Sunset on October 21, 2007. We have used the petition application form that is available on the NOP website. We have also included applicable flow charts for each of these six color categories. We look forward to working with you to assure that these colors from natural sources remain on the NOP National List well beyond October of 2007. If you have any questions or if you require any additional information, please do not hesitate to contact us.

Yours truly,

John T. Martin  
Director, Scientific & Regulatory Affairs  
WILD Flavors, Inc.  
P: 859-342-3798  
F: 859-342-3738  
Email: [jtmartin@wildflavors](mailto:jtmartin@wildflavors)

WILD Flavors, Inc.

WILD Flavors, Inc.  
1261 Pacific Avenue  
Erlanger, KY 41018 USA

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(888) WILD Flavors  
Facsimile: (859) 342-3610

# EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

**Category 1. Adverse impacts on humans or the environment?**  
CFR 73.95

Substance : beta-Carotene Color 21

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP, petition, regulatory agency, other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			21 CFR 73.95
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		

<sup>1</sup> If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Category 2. Is the Substance Essential for Organic Production?** Substance beta-Carotene Color 21 CFR 73.95

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP, petition, regulatory agency, other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]		X		
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			
4. Is there a natural source of the substance? [§205.600 b.1]	X			Fermentation of mold
5. Is there an organic substitute? [§205.600 b.1]		X		
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Is there any alternative substances? [§6518 m.6]		X		
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Category 3. Is the substance compatible with organic production practices?**

Substance beta-Carotene Color 21 CFR 73.95

Question	Yes	No	N/A <sup>1</sup>	Documentation (CFR, petition, regulatory agency, other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			X	
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]	X			
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		
a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Item A** – This petition involves the continued inclusion of exempt colors of natural beta-Carotene produced from mold fermentation described in 21 CFR 73.95 as a non-agricultural (non-organic) substance allowed in or on processed products labeled as “organic” or “made with organic”.

**Item B**

- 1.) beta-Carotene Color from natural sources
- 2.) WILD Flavors, Inc. 1261 Pacific Avenue Erlanger, KY 41018 859-342-3600
- 3.) To add color to food/beverages using exempt colorants from natural sources of beta-carotene
- 4.) Not intended for use on crops or livestock. Adding color is the mode of action.
- 5.) See attached flow chart
- 6.) Not applicable – WILD Flavors is not currently a certified manufacturer/handler
- 7.) Refer to 21 CFR 73.95
- 8.) 7235-40-7
- 9.) Refer to evaluation criteria
- 10.) Not applicable – MSDS available upon request.
- 11.) All categories of natural beta-Carotene colors are approved for use in accordance with 21 CFR 73.95 and are GRAS.
- 12.) Non-synthetic colors should remain on the National List as described in 7 CFR 205.605

Form NOPLIST2. Full Board Transmittal to NOP

Decision Sheets  
April 1, 2004

# NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: _____	Substance: _____																								
Committee: <b>Crops</b> <b>Livestock</b> <b>Handling</b>																									
<p><b>A. Evaluation Criteria (Documentation attached; committee recommendation attached)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;"></td> <td style="text-align: right; font-weight: bold;">Criteria Satisfied?</td> </tr> <tr> <td>4. Impact on humans and environment</td> <td style="text-align: right;">Yes    No    (see B below)</td> </tr> <tr> <td>5. Availability criteria</td> <td style="text-align: right;">Yes    No    (see B below)</td> </tr> <tr> <td>6. Compatibility &amp; consistency</td> <td style="text-align: right;">Yes    No    (see B below)</td> </tr> </table>			Criteria Satisfied?	4. Impact on humans and environment	Yes    No    (see B below)	5. Availability criteria	Yes    No    (see B below)	6. Compatibility & consistency	Yes    No    (see B below)																
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6. Compatibility & consistency	Yes    No    (see B below)																								
<p><b>B. Substance fails criteria?</b></p> <p>Criteria category: _____</p> <p>Comments: _____</p>	<p><b>C. Proposed Annotation:</b> _____</p> <hr/> <p><b>Basis for annotation:</b></p> <p>To meet criteria above: ____ Criteria: _____</p> <p>Other regulatory criteria: ____ Citation: _____</p>																								
<p><b>D. Recommended Committee Action &amp; Vote:</b>    Motion by: _____</p> <p style="text-align: center;">Seconded: _____</p> <div style="display: flex; align-items: flex-start; margin-top: 10px;"> <div style="width: 25%;"> <p><u>Vote:</u></p> <p>Yes: _____</p> <p>No: _____</p> <p>Abstain: _____</p> </div> <table border="1" style="width: 75%; border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 5px;">Agricultural</td> <td style="width: 20px;"></td> <td style="padding: 5px;">Nonagricultural</td> <td style="width: 20px;"></td> <td style="padding: 5px;">Crops</td> <td style="width: 20px;"></td> </tr> <tr> <td style="padding: 5px;">Synthetic</td> <td></td> <td style="padding: 5px;">Not synthetic</td> <td></td> <td style="padding: 5px;">Livestock</td> <td></td> </tr> <tr> <td style="padding: 5px;">Allowed<sup>1</sup></td> <td></td> <td style="padding: 5px;">Prohibited<sup>2</sup></td> <td></td> <td style="padding: 5px;">Handling</td> <td></td> </tr> <tr> <td style="padding: 5px;">No restriction</td> <td></td> <td style="padding: 5px;">Deferred<sup>4</sup></td> <td></td> <td style="padding: 5px;">Rejected<sup>3</sup></td> <td></td> </tr> </table> </div>		Agricultural		Nonagricultural		Crops		Synthetic		Not synthetic		Livestock		Allowed <sup>1</sup>		Prohibited <sup>2</sup>		Handling		No restriction		Deferred <sup>4</sup>		Rejected <sup>3</sup>	
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<p>1—substance voted to be added as "allowed" on National List</p> <p>Annotation: _____</p> <hr/> <p>2—substance to be added to "prohibited" paragraph of National List</p> <p>Describe why a prohibited substance: _____</p> <hr/> <p>3—substance was rejected by vote for amending National List</p> <p>Describe why material was rejected: _____</p> <hr/> <p>4—substance was recommended to be deferred</p> <p>Describe why deferred; if follow-up is needed. If follow-up needed, who will follow up _____</p> <hr/>																									

E. Approved by Committee Chair to transmit to NOSB:

\_\_\_\_\_  
Committee Chair

\_\_\_\_\_  
Date



# Beta-Carotene oil



